

# REGISTRATION REPORT

## Part B

### Section 0

Product Background, Regulatory Context and  
GAP information

Product code: ADM.03503.F.1.A

Product name(s): see Part A

Chemical active substances:

Fluxapyroxad, 75 g/L

Prothioconazole, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative  
as specified in Part A

Submission date: April 2022

MS Finalisation date: August 2023 (initial Core Assessment)

December 2023 (final Core Assessment)

### Version history

When	What
April 2022	Version 1 Applicant
August 2023	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b>. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p>
December 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are <b>highlighted in yellow</b>. Information no longer relevant is <del>struck through</del> and <del>shaded</del>.</p>

## **DATA PROTECTION CLAIM**

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03503.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03503.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

## **STATEMENT FOR OWNERSHIP**

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
- from a second party that has obtained permission from the owner of the data for this purpose or,
- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

## Table of Contents

<b>0</b>	<b>Product background, regulatory context and GAP information .....</b>	<b>5</b>
0.1	Introduction .....	5
0.1.1	Reason for application .....	5
0.1.2	Details of zRMS(s) and concerned MS .....	5
0.1.3	Regulatory history of the actives .....	5
0.1.3.1	Fluxapyroxad .....	5
0.1.3.2	Prothioconazole .....	6
0.1.4	Regulatory history of the product .....	8
0.2	zRMS conclusion.....	8
<b>Appendix 1</b>	<b>ALL intended uses .....</b>	<b>9</b>

## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application is for authorisation of ADM.03503.F.1.A, a new product containing fluxapyroxad and prothioconazole.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The application for approval was submitted on behalf of the sponsor ADAMA Makhteshim Ltd. (a member of ADAMA Agricultural Solutions Ltd. and its affiliates). For the applicant acting as country organisation/representative of ADAMA, please refer to Part A of the national assessment.

The active substance **fluxapyroxad** is approved under Reg. (EC) No 1107/2009 with effective date 1 August 2008 (Commission Implementing Regulations (EU) No 540/2011). The current expiry date is 31st May 2025.

The active substance **prothioconazole** is approved under Reg. (EC) No 1107/2009 with effective date 1 August 2008 (Commission Implementing Regulations (EU) No 540/2011).

Bayer Crop Science was the main notifier of the 1<sup>st</sup> EU review process. For the active substance prothioconazole, the applicant relies on data for which data protection period following Annex I listing has expired. As laid down in Commission Implementing Regulation (EU) No. 540/2011 and amending Commission Implementing Regulation (EU) 2021/745, the current expiry date of the approval of prothioconazole is 31<sup>st</sup> of July 2022.

There is no assessment of equivalence required for prothioconazole, since the source used in the product has already been assessed for equivalence by RMS UK. For further information on the source of prothioconazole used in ADM.03509.F.1.A please refer to the confidential Part C.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	SE	FI, LV, LT, EE
Central zone	PL	BE, NL, CZ, DE, IE, SK, HU, SI
Southern zone	MT	FR, IT, EL, ES, BU
Interzonal	Not applicable	

The product ADM.03503.F.1.A is currently not authorised in the EU

#### 0.1.3 Regulatory history of the actives

##### 0.1.3.1 Fluxapyroxad

**Table 0.1-2: Summary of regulatory history of CAS No: 907204-31-3**

Status	
Approved in EU	Y

<b>Status</b>	
Commission Implementing Regulation	Commission Implementing Regulation (EU) No 589/2012
RMS	United Kingdom
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2013
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2013
Date of final Commission (re-registration) deadline (Step 2)	30.06.2014
Current expiration of approval	31.05.2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States shall pay particular attention to the risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for fluxapyroxad (SANCO/10692/2012 Rev 2 1 June 2012 (updated 25 March 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 4 May 2012 (EFSA Journal 2012;10(1):2522).

**Table 0.1-3: Information on minimum purity of fluxapyroxad**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *
$\geq 950$ g/kg The impurity toluene must not exceed 1 g/kg in the technical material	$\geq 980$ g/kg impurity toluene 0.6 g/kg

\* Since EU approval, which was based on on a pilot plant production, the specification was updated based on data from large scale production (updated SANCO Report, 25 March 2021)

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

No such table is provided here. Information on deviating endpoints, if applicable at all, will be specified in the respective Part B documents.

### 0.1.3.2 Prothioconazole

**Table 0.1-4: Summary of regulatory history of CAS No: 178928-70-6 (Prothioconazole)**

<b>Status</b>	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/44/EC Commission Implementing Regulation (EU) No 540/2011 Commission Implementing Regulation (EU) 2020/869 Commission Implementing Regulation (EU) 2021/745  <u>Old legislation</u> Commission Implementing Regulation (EU) 2018/917

<b>Status</b>	
	Commission Implementing Regulation (EU) 2019/707
RMS	United Kingdom
Renewal RMS	Poland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	1 August 2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Step 1 under Dir. 91/414: 31 January 2009*
Date of final Commission (re-registration) deadline (Step 2)	Step 2 under Dir. 91/414: 31 January 2010*
Current expiration of approval	Extended to <del>31 July 2022</del> 15/08/2025**
Low risk substance or Candidate for Substitution?	No

\* Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include among other active substances prothioconazole.

\*\* ~~Commission Implementing Regulation (EU) No 2021/745~~ Commission Implementing Regulation (EU) 2023/918 of 4 May 2023

Issues that need to be considered as part of the EU approval are listed below.

The Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 provides specific provisions under Part B:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

In this overall assessment Member States, must pay particular attention to:

- the operator safety in spray applications. Conditions of use shall include adequate protective measures;
- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate;
- the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The concerned Member States shall request the submission of:

- information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin;
- a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds;
- information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment.

They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the approval.

The SANCO report for prothioconazole (SANCO/3923/07 – final, 10 December 2007 and the update 26 January 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12 July 2007.

**Table 0.1-5: Information on minimum purity of prothioconazole**

EU agreed minimum purity from Inclusion Directive or Implementing Regulation	Minimum purity of active substance used in the product / information on available equivalency report *, **
<p>≥ 970 g/kg</p> <p>The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:</p> <ul style="list-style-type: none"> <li>- Toluene: &lt; 5 g/kg</li> <li>- Prothioconazole- desthio (2-(1- chlorocyclopropyl)1-(2- chlorophenyl)-3- (1,2,4-triazol-1-yl)- propan-2-ol): &lt; 0,5 g/kg (LOD)</li> </ul> <p>(Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC and Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011)</p>	<p>≥ 980 g/kg</p> <p>Equivalence report available: yes</p> <p>RMS: UK</p>

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

No such table is provided here. Information on deviating endpoints, if applicable at all, will be specified in the respective Part B documents.

#### 0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

#### 0.2 zRMS conclusion

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.






## Appendix 1 ALL intended uses

PPP (product name/code): ADM.03503.F.1.A Formulation type: EC (a, b)  
Active substance 1: Fluxapyroxad Conc. of as 1: 75 g/L (c)  
Active substance 2: Prothioconazole Conc. of as 2: 150 g/L (c)  
Applicant: Country organisation/representative of ADAMA as given in Part A Professional use: ☒  
Zone(s): Central Zone Non professional use: ☐  
Verified by MS: Yes ~~No~~  
Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use - No. (e)	Member state(s)	Crop and/or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)	Overall conclusions								
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in	Efficacy	
Zonal uses (field or outdoor uses, certain types of protected crops)																						
1	Belgium	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. tritici, <i>Fusarium</i> + <del>microdochium</del>	foliar, spraying, overall	-/ BBCH 30-69 spring; <b>Fusarium - BBCH 61-69</b>	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A	
																			A Remaining		C <i>Fusarium</i>	
2	Belgium	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. hordei	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A	
																			A Remaining			

3	Belgium	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
4	Belgium	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
5	Netherlands	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. tritici, <i>Fusarium</i> + <i>microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <b>Fusarium - BBCH 61-69</b>	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		C <i>Fusarium</i>
6	Netherlands	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. hordei	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
7	Netherlands	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		

8	Nether-lands	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
9	Czechia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. tritici, <i>Fusarium + microdo-chium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <b>Fusari-um - BBCH 61-69</b>	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining	 <i>Fusa-rium</i>	
10	Czechia	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. hordei	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
11	Czechia	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	
																			A Remaining		
12	Czechia	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	
																			A Remaining		

1 3	Germa- ny	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. <del><i>tritici</i></del> <i>Erysiphe graminis</i> , <i>Fusarium</i> + <i>microdochium</i>	foliar, spraying, overall	-/ BBCH 30-59 69 spring; <i>Fusarium</i> - BBCH 60-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150 -400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		A
1 4	Germa- ny	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. <del><i>hordei</i></del> <i>Erysiphe graminis</i>	foliar, spraying, overall	-/ BBCH 30-59 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150 -400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
1 5	Germa- ny	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150 -400			A	A	R	A	A	R Aquatics R scenarios	A	
																			A Remaining		
1 6	Germa- ny	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i> <i>Erysiphe graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150 -400			A	A	R	A	A	R Aquatics R scenarios	A	
																			A Remaining		
1 7	Ireland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <i>Fusarium</i>	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A

				<i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. <i>tritici</i> , <i>Fusarium</i> + <i>microdo-</i> <i>chium</i>		um - BBCH 61-69												A Remaining		C <i>Fusa-</i> <i>rium</i>	
1 8	Ireland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. <i>hordei</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
1 9	Ireland	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
2 0	Ireland	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-</i> <i>repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
2 1	Poland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-</i> <i>repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. <i>tritici</i> , <i>Fusarium</i> + <i>microdo-</i> <i>chium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; um - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
2 2	Poland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> in HORVW only, <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A

				<i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. <i>hordei</i>														A Remaining			
2 3	Poland	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	N
																		A Remaining			
2 4	Poland	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																		A Remaining			
2 5	Slo- vakia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. <i>tritici</i> , <i>Fusarium</i> + <i>microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <i>Fusarium</i> - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																		A Remaining		C <i>Fusarium</i>	
2 6	Slo- vakia	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. <i>hordei</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																		A Remaining			
2 7	Slo- vakia	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																		A Remaining			

28	Slovakia	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A <i>P. recondita</i> , <i>B. graminis</i>
																			A Remaining		C <i>Z. tritici</i> , <i>D. tritici-repentis</i>
29	Hungary	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. tritici, <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <i>Fusarium</i> - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		C <i>Fusarium</i>
30	Hungary	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. hordei	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
31	Hungary	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A
																			A Remaining		
32	Hungary	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR)	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A	A	R	A	A	R Aquatics R scenarios	A	A <i>P. recondita</i> , <i>B. graminis</i>

				<i>Blumeria graminis</i>																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
--	--	--	--	--------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--



																		A Remaining	C Z. <i>tritici</i> , D. <i>tritici-</i> <i>re-</i> <i>pentis</i>
--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	----------------	---

(d)	Select relevant
(e)	Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column I
(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Black-  
8 well, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.  
9 The maximum number of application possible under practical conditions of use must be provided.  
10 Minimum interval (in days) between applications of the same product  
11 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty  
12 rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
13 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g,  
14 kg or L product / ha).  
15 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be men-  
16 tioned under “application: method/kind”.  
17 PHI - minimum pre-harvest interval  
18 Remarks may include: Extent of use/economic importance/restrictions  
19 Overall conclusions - explanation for the column 15 is below \*

\* Explanation for column 15 “Overall conclusions”

Explanation for column 15 – Overall conclusions	
A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use